Updated Instructions for Water Cleanliness

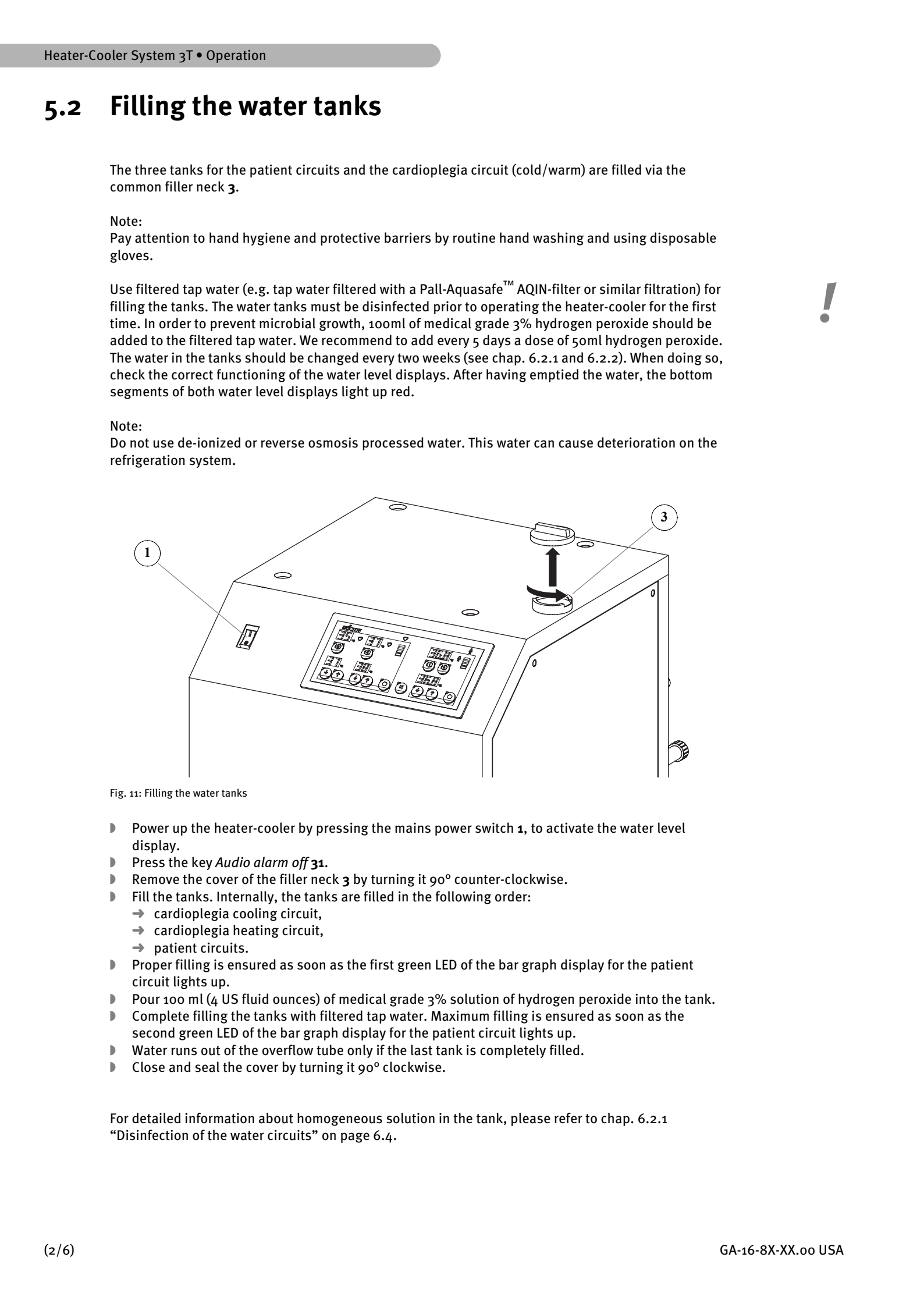
Please note:
These “Updated Instructions for Water Cleanliness” replace previous water cleaning instructions for the 3T Heater-Cooler.

5.2 Filling the water tanks

The three tanks for the patient circuits and the cardioplegia circuit (cold/warm) are filled via the common filler neck **3**.

Note:
Pay attention to hand hygiene and protective barriers by routine hand washing and using disposable gloves.

Use filtered tap water (e.g. tap water filtered with a Pall-Aquasafe™ AQIN-filter or similar filtration) for filling the tanks. The water tanks must be disinfected prior to operating the heater-cooler for the first time. In order to prevent microbial growth, 100ml of medical grade 3% hydrogen peroxide should be added to the filtered tap water. We recommend to add every 5 days a dose of 50ml hydrogen peroxide. The water in the tanks should be changed every two weeks (see chap. 6.2.1 and 6.2.2). When doing so, check the correct functioning of the water level displays. After having emptied the water, the bottom segments of both water level displays light up red.



Note:
Do not use de-ionized or reverse osmosis processed water. This water can cause deterioration on the refrigeration system.

Fig. 11: Filling the water tanks

- Power up the heater-cooler by pressing the mains power switch **1**, to activate the water level display.
- Press the key *Audio alarm off* **31**.
- Remove the cover of the filler neck **3** by turning it 90° counter-clockwise.
- Fill the tanks. Internally, the tanks are filled in the following order:
  - ➜ cardioplegia cooling circuit,
  - ➜ cardioplegia heating circuit,
  - ➜ patient circuits.
- Proper filling is ensured as soon as the first green LED of the bar graph display for the patient circuit lights up.
- Pour 100 ml (4 US fluid ounces) of medical grade 3% solution of hydrogen peroxide into the tank.
- Complete filling the tanks with filtered tap water. Maximum filling is ensured as soon as the second green LED of the bar graph display for the patient circuit lights up.
- Water runs out of the overflow tube only if the last tank is completely filled.
- Close and seal the cover by turning it 90° clockwise.

For detailed information about homogeneous solution in the tank, please refer to chap. 6.2.1 “Disinfection of the water circuits” on page 6.4.

6.2.1 Disinfection of the water circuits

The water circuits **must** be disinfected prior to operating the heater-cooler for the first time, when placing the unit in storage and if the hydrogen peroxide procedure was not routinely performed. In order to prevent microbial growth, we recommend performing the disinfection cycle every 3 months.
The Heater-Cooler 3T water circuits include the pump, heating and cooling tanks, fittings and all interconnecting tubing.

For disinfection of the water circuits, use Clorox® Regular-Bleach, a bleach solution containing 6% sodium hypochlorite.
Please be aware, that only Clorox® Regular-Bleach has been tested for the use with the heater-cooler. Even other disinfectants with the same sodium hypochlorite concentration can contain different additives, which may influence the material compatibility. Thus, the use of any other disinfectant is explicitly not recommended.

- Thoroughly follow the manufacturer safety instructions contained on the Clorox® Regular-Bleach during the disinfection cycle.

- Clorox® Regular-Bleach must only be used pre- and postoperatively, **never intraoperatively**.

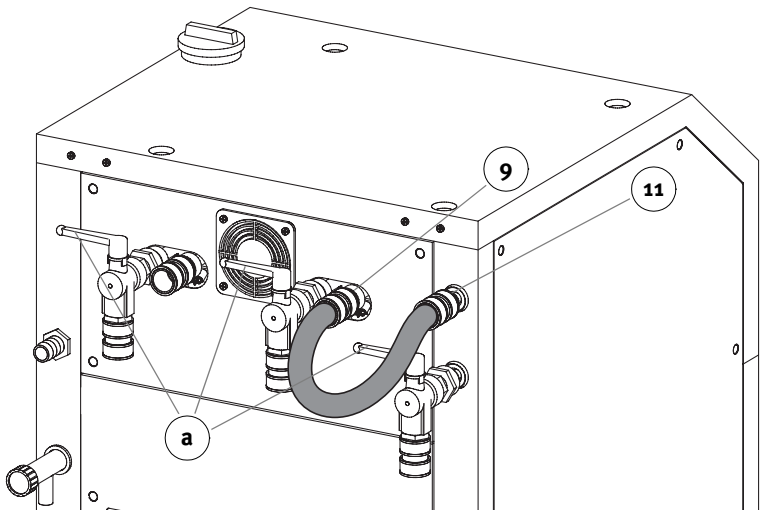
- Pay attention to hand hygiene and protective barriers by routine hand washing and using disposable gloves.

Perform the following steps for disinfection:

- Drain water tanks.
- Assure the three valves on the back of the heater-cooler are closed.
- Press the mains power switch **1** to power up the heater-cooler.
- Press the key *Audio alarm off* **31**.
- Unscrew the cover of the filler neck **3** (see chap. 5.2 “Filling the water tanks” on page 5.2).
- Fill the water tanks with filtered tap water until the first green LED of the bar graph display for the patient circuit lights up.
- Add 200 ml (6.76 US fluid ounces) of Clorox® Regular-Bleach to the tank.
- Complete filling the tanks with filtered tap water until the second green LED of the bar graph display for the patient circuit lights up.

To ensure a homogeneous solution in the tanks:

- Close the cover of the filler neck.
- Assure the three valves **a** on the back of the heater-cooler are closed.
- Establish a connection between the inlet of the cardioplegia circuit **11** and the inlet of one of the patient circuits **9**.



Please note that a temperature alarm can be triggered if the temperature deviates in the individual tanks.
To avoid this alarm, adjust the set temperature values of the warm cardioplegia circuit and the patient circuit to approx. 20 °C (see “Adjusting the set values”).

Starting the cold cardioplegia circuit

- Press the key *Circuit Start/ Stop* **33** on the heater-cooler to start the **cooling** circuit (cooling tank= blue dot).

➜ The green key LEDs on the heater-cooler flash alternately.

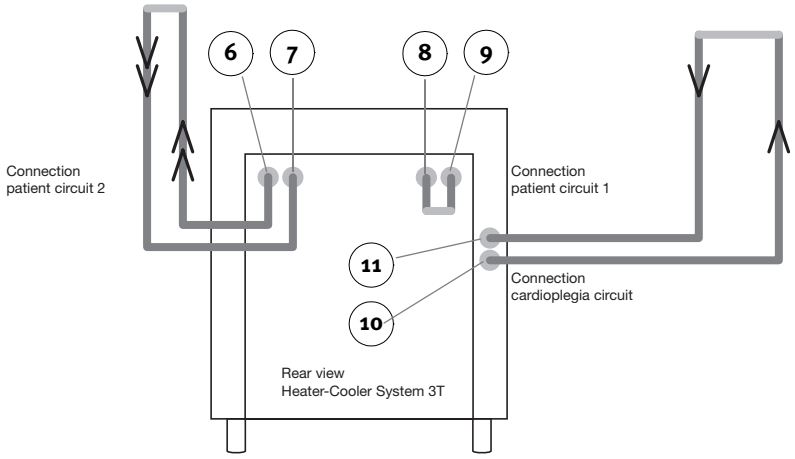
The water flow changes the fill level in the tanks:

➜ If the orange LED flashes, add 0.2 to 0.5 liters of filtered water as quickly as possible. Alarm is triggered if the level drops any further (see “Water level alarm” on page 5.10).

- After 5 minutes, press the key *Circuit Start/Stop* again to stop the circuit.

Disinfection of the tubing system (circulation through all circuits)

- Remove connection between the inlet of the cardioplegia circuit **11** and the inlet of the patient circuits **9**.
- Establish connections between all circuits (**6** and **7**, **8** and **9**, **10** and **11**). For the short circuit of the tubing, use a tubing connector 1/2", short circuit tubing bridge (part number 73-300-160).
- Open the three venting valves at the rear of the heater-cooler.



Starting the patient and warm cardioplegia circuits

- Press the keys *Circuit Start/ Stop* **32** and **33** (warm) on the heater-cooler to start the circuits.

➜ The green key LEDs on the heater-cooler flash alternately.

Stopping all circuits

- After 10 minutes, close the valves on the back of the heater-cooler and drain the connecting tubings.
- Press the keys *Circuit Start/ Stop* again to stop all circuits.

➜ The water flow is stopped.

➜ The green key LEDs go out.

Flushing the water tanks:

- Open the drain valves **12** and **13**.
- Drain the water containing the Clorox® Regular-Bleach and adhere to the regulations of your hospital for proper disposal.

Rinse the tanks two (2) times as follows:

- Fill the tanks with filtered tap water.
- Circulate the water for approximately 3 minutes by pressing the key *Circuit Start/ Stop*.
- Stop circulation and drain the water.

Heater-cooler return to service

Having completed the disinfection, close the drain valves and fill the tanks again with filtered tap water.

Note:

Do not use de-ionized or reverse osmosis processed water. This water can cause deterioration on the refrigeration system.

Heater-cooler placed in storage

- When all fluid has been removed from the unit, disconnect hoses and wipe unit clean.

➜ Unit can now be stored.

6.2.2 Protecting the water circuits from microbial growth

The water in the water circuits should be changed every two weeks and hydrogen peroxide added to prevent microbial growth.

Note:
Pay attention to hand hygiene and protective barriers by routine hand washing and using disposable gloves.

Filling and changing the water (change water every 2 weeks)

- Drain water tanks and ensure the drain valves are closed.
- Press the mains power switch **1** to power up the heater-cooler.
- Press the key *Audio alarm off* **31**.
- Unscrew the cover of the filler neck **3** (see chap.5.2 “Filling the water tanks” on page 5.2).
- Fill the water tanks with filtered tap water until the first green LED of the bar graph display for the patient circuit lights up.
- Pour 100 ml (4 US fluid ounces) of medical grade 3% solution of hydrogen peroxide into the tank.
- Complete filling the tanks with filtered tap water until the second green LED of the bar graph display for the patient circuit lights up.

To ensure a homogeneous solution in the tanks:
- Close the cover of the filler neck.
- Close the three venting valves at the rear of the heater-cooler.
- Establish a connection between the inlet of the cardioplegia circuit **11** and the inlet of the patient circuits **9**.
- Press the key *Circuit Start/ Stop* **33** on the heater-cooler to start the cooling circuit (cooling tank= blue dot).
- After 5 minutes, press the key *Circuit Start/ Stop* again to stop the circuit.

Maintaining hydrogen peroxide concentration (after 5 days)

- The concentration of hydrogen peroxide decreases with time. To maintain proper levels, add 50 ml (2 US fluid ounces) of 3% hydrogen peroxide solution to the tanks after 5 days.

To ensure a homogeneous solution in the tanks:
- Close the cover of the filler neck.
- Close the three venting valves at the rear of the heater-cooler.
- Establish a connection between the inlet of the cardioplegia circuit **11** and the inlet of the patient circuits **9**.
- Press the key *Circuit Start/ Stop* **33** on the heater-cooler to start the cooling circuit (cooling tank= blue dot).
- After 5 minutes, press the key *Circuit Start/ Stop* again to stop the circuit.

Note:
Do not use de-ionized or reverse osmosis processed water. This water can cause deterioration on the refrigeration system.